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Mumbai: Dr. Reddy's Laboratories, India's leading pharmaceutical company, recently launched Montelukast Sodium Tablets and Montelukast Sodium Chewable Tablets in the US market. They are the bioequivalent generic versions of SINGULAIR tablets and chewable tablets, following the approval by the United States Food & Drug Administration (USFDA) of Dr. Reddy's ANDA.

The SINGULAIR tablets and chewable tablets brand has had US sales of approximately $3.6 billion and $1.14 billion respectively for the most recent twelve months ending March 2012 according to IMS Health.

Mylan Pharmaceuticals too has received final approval from the US FDA for its Abbreviated New Drug Application (ANDA) for the Montelukast Sodium Tablets, 10 mg, and Montelukast Sodium Chewable Tablets, 4 mg and 5 mg. These products are indicated for the prophylaxis and chronic treatment of asthma in patients two years of age and older, for prevention of exercise-induced bronchoconstriction in patients 15 years of age and older, and for the relief of symptoms of seasonal and perennial allergic rhinitis in patients two years of age and older.

Montelukast Sodium Tablets, 10 mg, had US sales of approximately $3.7 billion for 12 months ending June 30, 2012, and Montelukast Sodium Chewable Tablets, 4 mg and 5 mg, had US sales of approximately $1.2 billion for the 12 months ending June 30, 2012, according to IMS Health. Mylan has begun shipping both of these products to the US.